

Rocky Flats Environmental Technology Site

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GRADED VALIDATION

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1. PURPOSE

This procedure provides guidelines for determining the levels of inspection (25% to 100%) that will be used to determine the quality of laboratory analyses performed on environmental samples collected as part of the ongoing environmental management activities at the Rocky Flats Plant (RFP).

This procedure specifically supports the activities of the EG&G Rocky Flats, Inc. (EG&G) Environmental Restoration Program Division (ERPD).

2. SCOPE

This procedure applies to the Environmental Restoration Program Division/Sample Management Office (ERPD/SMO), validation subcontractor(s), and subcontracted analytical laboratories providing data to the SMO.

This procedure addresses the graded validation process including:

- Determining the levels of inspection.
- Segregating the sample delivery groups (SDGs).
- Changing inspection levels of SDGs.
- Handling rejected SDGs.

This procedure does not detail the validation process or describe the methods employed by the ERM/SMO for trending and evaluating subcontracted laboratories.

3. OVERVIEW

The graded validation plan assumes that all SDGs are created equally, for example, that there are an equal number of samples and an equal number of analytes per sample.

Originally, the plan indicated time durations for validation at the full inspection level; the plan has now been amended to include the minimum number of packages required to be validated for a 3-month or 6-month duration. This change has been made because a laboratory may not receive an appropriate number of packages within a 6-month or 3-month time duration because of the nature of sampling and laboratory capacity. This process also allows this procedure to be internally consistent, since changing levels of inspection are dependent upon the number of packages output, not time periods.

4. DEFINITIONS

4.1 Definitions

Full Inspection Level. The level of inspection appropriate for newly contracted laboratories, new methods, laboratory re-admission to the program after resolution of technical or quality problems, and for designated special projects.

Graded Validation. The concept for the process of validating laboratory data for EG&G Environmental Management samples. The concept consists of random selection of SDGs from each analytical laboratory where 100% validation is administered at varying levels of inspection.

Level of Inspection. The level of inspection chosen after laboratory performance and trending are evaluated. The four levels are: reduced (25%), normal (50%), tightened (75%), and full (100%). The levels correspond to that percentage of SDGs which are randomly selected to undergo validation.

Lot. The output (SDGs) of an individual subcontracted laboratory for the period of one month.

Normal Inspection Level. The level of inspection appropriate at the start of an inspection and for laboratories of acceptable but not exceptional quality. The percentage of SDGs to be validated for normal inspection is 50%.

Operable Unit (OU). The designated group of individual hazardous substance sites within specific areas of the RFP.

Reduced Inspection Level. The appropriate level of inspection when observed and documented past performance indicates that a laboratory is of exceptional quality. The percentage of SDGs to be validated for reduced inspection is 25%.

Rocky Flats Environmental Database System (RFEDS). The repository and supporting applications that manage the storage of environmental site characterization data from RFP.

Sample Delivery Group (SDG). Samples received at the laboratory in one or more shipments. Samples from more than one chain-of-custody may be combined to form a single group. Samples in a SDG are validated as a group.

Tightened Inspection Level. The level of inspection appropriate when observed past performance indicates that a laboratory may not be producing data packages of acceptable quality. The percentage of SDGs to be validated for tightened inspection is 75%.

Validation. The independent qualification of laboratory data using functional guidelines.

4.2 Acronyms

CTR	Contractor Technical Representative
ERM	Environmental Restoration Management
OU	Operable Unit
RFEDS	Rocky Flats Environmental Database System
SDG	Sample Delivery Group
SMO	Sample Management Office

5. **RESPONSIBILITIES**

5.1 Contractor Technical Representative (CTR)

Enforces the technical and contractual obligations of the subcontractors.

Informs the validation subcontractor of the level of inspection to be used for each laboratory, and which SDGs require validation.

Ensures that laboratory SDG numbers are provided to the RFEDS Manager or designee for entry into the random number selector (computer software).

Changes the level inspection based on monthly validation status.

5.2 Rocky Flats Environmental Database System Manager

Provides the CTR with the randomly selected SDGs, (by laboratory), that require validation.

Maintains a database table that contains the active laboratories lists of submitted SDGs, SDG lots, and the SDGs chosen for validation.

Responsible for the input, output, and quality assurance of the RFP environmental data.

5.3 Rocky Flats Plant Program Managers

Provide the applicable sample numbers and locations of samples requiring full inspection to the CTR of the validation subcontract.

5.4 Sample Management Office

Manages and maintains the laboratory subcontracts, sample tracking, data receipt, data validation, and data dissemination records.

5.5 Validation Subcontractor

Receives the completed SDG data packages from the subcontracted laboratories.

Receives the validation instructions from the CTR.

Performs validation on the SDGs and provides timely and correct validation reports to the CTR. These reports will include weekly oral reports to apprise the CTR of potential laboratory problems.

6. INSTRUCTIONS

6.1 Determining the Level of Inspection

NOTE *The unit of product for inspection is the lot. The unit of product for validation is the SDG. An SDG may contain individual sub-SDGs that undergo the validation process.*

CTR

- [1] Determine the level of inspection for each laboratory lot.
- [2] Inform the validation subcontractor on a monthly basis as to which level of inspection each laboratory belongs.
- [3] Inform the validation subcontractor which SDGs have been randomly selected for validation.
- [4] Inform the validation subcontractor which SDGs have samples that require full inspection.

RFP Program Manager

- [5] Provide the CTR with identification and locations of samples (or projects) that require full inspection.

Validation Subcontractor

- [6] Perform full inspection on the following types of SDGs:
 - SDGs from newly contracted laboratories for a validation period of six months or a minimum of 12 SDGs
 - SDGs which contain a new method performed by a laboratory for a validation period of three months or a minimum of six SDGs
 - SDGs from laboratories re-admitted to the program after resolution of technical or quality problems for a validation period of three months or a minimum of six SDG.
 - SDGs containing samples for which the RFP Program Manager has requested full inspection
 - Lots containing SDGs rejected from Section 6.4, Handling Rejected SDGs
- [7] Perform validation on the following types of SDGs at the inspection level as identified by the CTR for the appropriate laboratory:
 - All OU analytical work
 - Groundwater samples
 - Surface water samples
 - Special project samples

6.1 Determining the Level of Inspection**Validation Subcontractor (continued)**

- [8] Prepare and submit validation reports to the CTR.
- [9] Inform the CTR weekly of potential laboratory problems which may lead to rejected SDGs.

6.2 Segregating SDGs

NOTE *All SDGs at the same inspection level must be equally likely to be validated. The SMO must not preferentially choose SDGs that are more or less likely to have defects.*

RFEDS Manager

- [1] Provide a list by laboratory of randomly selected (by utilizing statistical software) SDGs to be validated for the given month.
- [2] Maintain a database table containing contracted laboratories with complete lists of lots, submitted SDGs, and SDGs chosen for validation.
- [3] Place a Z designation for complete SDGs which contain samples not requiring validation.

Examples include samples for which data have never been reviewed in any fashion, for example, some historical data for which the documentation is not available, samples for which data results are available and for which no raw data exist, samples collected from the National Pollutant Discharge Elimination System (NPDES), and samples collected from the decontamination pad (samples beginning with the prefix DW).

- [4] Designate the month and year in the appropriate database fields for those SDGs which have not been randomly selected for validation.

SMO

- [5] Ensure that each lot has been inspected and that randomly selected SDGs have been validated.

NOTE *Individual SDGs or sub-SDGs, that have not actually undergone validation but belong to a lot that has had validation applied, will not have assigned qualifiers.*

- [6] Identify the unvalidated SDGs, (and respective samples), as belonging to a validated lot using the two-digit year and the two-digit month in which the lot was validated, for example, using 9407 for July 1994.

6.2 Segregating SDGs (continued)**Validation Subcontractor**

- [7] Segregate radiochemistry SDGs for inspection according to the following instrumentation:
- Alpha spectrometry
 - Gamma spectrometry
 - Liquid scintillation
 - Gross alpha/beta by gas proportional counting
 - Radiometric strontium, cesium, and radium-228 by gas proportional counting
 - Radium-226 by radon emanation using a Lucas cell
 - Kinetic laser phosphorimetry
- [8] Segregate general chemistry SDGs for inspection according to the following:
- Volatile organics
 - Semi-volatile organics
 - Other organics (herbicides, dioxins, polychlorinated biphenyls, toxicity leaching - method 1311)
 - Water quality
 - Pesticides
 - Metals
- [9] Place a Z designation on the samples *within* an SDG that do not require validation. Examples include samples for which data have never been reviewed in any fashion, for example, some historical data for which the documentation is not available, samples for which data results are available and for which no raw data exist, samples collected from the NPDES, and samples collected from the decontamination pad (samples beginning with the prefix DW).
- [10] Perform a normal level inspection for a period of two months for each laboratory (except those covered under Step 6.1.[6]) at the initiation of this procedure.
- [11] Perform a 100% validation for the individual or sub-SDGs at one of the following four levels of inspection as instructed by the CTR:
- 25% of the submitted SDGs at the reduced level
 - 50% of the submitted SDGs at the normal level
 - 75% of the submitted SDGs at the tightened level
 - 100% of the submitted SDGs at the full level

6.3 Changing the Inspection Levels of the SDGs**CTR**

- [1] Change the level of inspection when any of the following conditions exist:
- [A] IF validation results in a rejected SDG,
THEN change the inspection level from the normal level to the tightened level of inspection.
 - [B] IF the validation results in three acceptable SDGs,
THEN change the inspection level from the normal level to the reduced level by considering the past performance of the laboratory.
 - [C] IF any major changes occur in:
 - Instrumentation
 - Key analytical personnel during a reduced inspection,THEN change the inspection level from the reduced level to the normal level of inspection.
 - [D] IF an SDG is rejected during a reduced level inspection,
THEN change the inspection level from the reduced level to the normal level of inspection.
 - [E] IF a tightened level of inspection results in three acceptable SDGs,
THEN change the inspection level from the tightened level to the normal level.

6.4 Handling Rejected SDGs**SMO**

- [1] Inform the validation subcontractor of the additional SDGs requiring full inspection within the lot that contained any rejected SDG.

Validation Subcontractor

- [2] Perform a full inspection of all SDGs remaining in the rejected lot to determine which SDGs should also be rejected.
- [3] Identify all problems in the rejected lot.
- [4] Notify the laboratory to resolve problems, when possible, by supplying missing documentation as necessary.

7. RECORDS

Management of all records is consistent with 1-77000-RM-001, Records Management Guidance for Records Sources.

The records generated as a result of this procedure are considered quality records and are managed in accordance with 2-G18-ER-ADM-17.01, Records Capture and Transmittal. The records generated as a result of this procedure are also considered potential Administrative Records and are managed in accordance with 3-21000-ADM-17.02, Administrative Records Screening and Processing.

There are no nonquality records generated by this procedure.

SMO

[1] Maintain the following records in accordance with 1-77000-RM-001, Records Management Guidance for Records Sources:

- Database tables of lots
- SDGs selected for validation
- Laboratory levels of inspection by month
- Special samples or projects designated for full inspection

8. REFERENCES

1-77000-RM-001, Records Management Guidance for Records Sources

2-G18-ER-ADM-17.01, Records Capture and Transmittal

3-21000-ADM-17.02, Administrative Records Screening and Processing